This record is a partial extract of the original cable. The full text of the original cable is not available.

UNCLAS BRASILIA 001146

SIPDIS

STATE PASS TO FDA/INTL PROGRAMS FOR ASSOCIATE DIRECTOR FOR
THE AMERICAS DESK CHARLES GAYLORD

E.O. 12958: N/A
TAGS: TBIO KSCA OSCI BR
SUBJECT: APPROVAL OF FDA RESEARCH PROJECT ENTITLED
"ASSESSMENT OF IDURONATE-2-SULFATASE IN MPS II (HUNTER
SYNDROME) (AIM) PIVOTAL TRIAL" WITH RECOMMENDATION

REF: (A) 04 BRASILIA 01922, (B) 04 STATE 164536

CORRECTED VERSION - PLEASE SEE SUBJECT LINE

¶1. On April 18, 2005, Embassy received from the Brazilian Ministry of Foreign Affairs, Division of Science and Technology, (DCTEC/MFA) an official notification (number 152, dated April 15, 2005) approving the research project proposal entitled "ASSESSMENT OF IDURONATE-2-SULFATASE IN MPS II (HUNTER SYNDROME) (AIM) PIVOTAL TRIAL," (number RFA-FDA-OPD-2004-1), under the direction of Dr. Roberto Giugliani, of Hospital das Clinicas de Porto Alegre, Rio Grande do Sul. An informal translation of the approval notice follows:

¶2. Begin text:

Dear Ms. Norman,

I hereby inform you that the Brazilian government has reviewed the project entitled "Assessment of Iduronate-2-Sulfatase in MPS II (Hunter syndrome) (AIM) Pivotal Trial" to be developed by Dr. Roberto Giugliani from Hospital das Clinicas de Porto Alegre, UFRGS, with financial support from the Food and Drug Administration (FDA).

2) The aforesaid protocol was approved with a recommendation. Please see National Commission on Ethics in Research (CONEP) considerations below:

a)"requests in referred opinion have been duly complied with. However, it is recommended that:

1 - the sentence "or until sponsor decides to discontinue the study" in subclause "Continued Protein Supply" be removed.

2 - researchers file a report with CEP assessing advantages/needs for continued drug use.

b) the project generally meets the basic requirements in Resolutions CNS 196/96 and 292/99 on Guidelines and Regulations for Research Involving Human Beings;

c) the project was approved by the Committee of Ethics in Research (CEP) of the aforementioned institution.
In consideration of the above information, CONEP, drawing its authority from Resolution CNS 196/96, declares its approval of the proposed research project which will also include CEP monitoring of recommendations set forth in a) above."

3) The Ministry of Science and Technology (MCT) has reviewed and approved the above mentioned protocol, but has reminded Brazilian researchers that under the legislation in force they must request the required authorization from the Council for Scientific and Technological Development (CNPq) prior to shipping collected data and/or biological material to foreign countries.

Yours truly,

Vergniaud Elyseu Filho
(Signature)
Head of the Division of Science and Technology
Ministry of Foreign Affairs

End text of translation.

¶3. The Embassy sees no adverse foreign policy implications with respect to this research project. We reiterate the importance of complying with Brazilian law on the export of data and biological material and medical research involving human beings.

¶4. Embassy Science and Health Counselor Patricia Norman would like to establish contact with the International Officer at FDA responsible for this grant. Please send email to normanpd@state.gov
DANILOVICH